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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,575	01/16/2002	Nishizumi Nishimuta	018995-452	4939

7590 01/15/2004

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EXAMINER	
KIM, VICKIE Y	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,575	NISHIMUTA ET AL.	
	Examiner	Art Unit	
	Vickie Kim	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-31* is/are pending in the application.

4a) Of the above claim(s) *4,5,7,8,15 and 17-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,9-14 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11/14*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed 10/16/2003. Upon entering the amendment, the claims 1 and 6 are amended and the claim 16 is canceled.

2. The claims 1-15 and 17-31 are pending. The elected claims 1-3, 9-14 and 31 are presented for the examination. The non-elected claims 4-8 and 15 and 17-30 are withdrawn from the consideration.

Information Disclosure Statement(IDS)

The status inquiry was requested for the information disclosure statement (IDS) submitted on Nov. 14, 2002. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

Claim Objections

3. Claim 6 is objected to because of the following informalities: Claim 6 is amended to correct the dependency. Claim 6 is now dependent on claim 4. However, the claim 4 which the claim 6 is dependent on is found to be withdrawn. In previous communication, applicantsidentified that claims 1-3, 6, 9-14 , 16 and 31 are readable for the elected species(tinidazole). Thus, changing the dependency of claim 6 to claim 3(pending) or canceling claim 6 would obviate this objection. Appropriate correction is required.

Response to Arguments

Applicant's arguments filed 10/16/2003 have been fully considered but are moot in view of the new ground(s) of rejection due to the scope changes made into the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 6, 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al(WO98/27960) in view of Fleischer(1999, abstract only); or Fleischer(1999) and Miller et al(1980, abstract only).

Goodman et al(WO'960, hereafter) teaches a viscous hydrogel topical composition containing nitroimidazole (e.g. tinidazole) for treating inflamed skin diseases such as rosacea and eczema, see abstract and page 1, lines 12-15, especially example 1. The exemplified species, tinidazole in a therapeutically effective amount about 0.75% is well taught and encompassed by the scope of the claims.

Applicants' claims differ from WO'960 because they specifically require atopic dermatitis.

However, it would have been obvious to one of ordairy skill in the art at the time of the invention was made to substitute the inflamed skin diseases(WO'960) with atopic dermatitis when WO'960 is taken in view of Fleischer(1999); or Fleischer and

Miller(1980) together because later references teach the deficiency found un Goodman et al's teaching.

Firstly, Fleischer teaches that atopic dermatitis is a form of eczema(i.e. a chronic and relapsing form of eczema, see entire abstract.

Secondly, Fleischer also teaches that immune regulation plays an important role in the cause of atopic dermatitis and therefore, immunosuppressants are effectively used in the treatment of atopic dermatitis. Miller teaches that tinidazole is effective immunosuppressant in vivo, see abstract.

Thus, one would have been motivated to prophylactically treat atopic dermatitits using tinidazole because treating an eczema could prevent further undesirable implications(e.g. relapsing or transforming into chronic eczema) which is in turn becoming atopic dermatitis because tinidazole is proven to be effective therapeutic modality for eczema or other inflamed skin diseases. If the immune regulation is considered to be the underlying mechanism for the atopic dermatitis, one would have been motivated to do make such substitution with assurance and reasonable expectation of success because Miller teaches that tinidazole as an effective immunosuppressant in vivo.

One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to improve patient's compliance by enhancing patient satisfaction and increasing the selection option.

These references are particularly pertinent and relevant because all the claimed species and their roles are well taught in the cited references when they are combined together. Thus, one would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

As mentioned in previous office action , claims 13-14 are properly included in this rejection because the combination (i.e. tinidazole and steroid) is conventional drug regimen(see PTO-892) to maximize the therapeutic efficacy by utilizing two drugs having different biological pathway and lowering the doses of active agents(used) which in turn reduces undesired side effects and manufacturing cost.

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6. Applicant's arguments filed 10/16/2003 have been fully considered but they are not persuasive. The allegations found in the remarks(10/16/2003) is directed to the substitution of tacrolimus with tinidazole, whereas the substitution suggested by examiner should be directed to the substitution of inflamed skin diseases(e.g. eczema) with atopic dermatitis. As clearly taught by the Fleischer, atopic dermatitis is a form of eczema(chronic and relapsed). Regardless underlying mechanism for the said diseases, effective treatment of eczema by tinidazole has been proven and treating exzema could prevent further implications including atopic dermatitis because eczema is beginning stage for atopic dermatitis and tinidazole treats eczema before transforming into the chronic stage.

If the immune regulation is considered to be the underlying mechanism for the atopic dermatitis, one would have been motivated to do make such substitution with assurance and reasonable expectation of success because Miller's teaching(i.e. tinidazole as an effective immunosuppressant in vivo) supports the said substitution.

Minor variations such as titration of effective drug dosages, selection of effective carriers or determination of effective routes of application, in order to make most effective treatment is considered to be well within the level of the skilled artisan and thus, obvious, absent evidence to the contrary. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

Conclusion

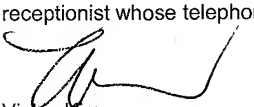
7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Primary Patent Examiner
Art unit 1614